EXHIBIT B

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ORANGE

THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Santa Clara County Counsel James R. Williams, Orange County District Attorney Tony Rackauckas, Los Angeles County Counsel Mary C. Wickham, and Oakland City Attorney Barbara J. Parker,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON, PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. 30-2014-00725287-CU-BT-CXC

Assigned for All Purposes To:
Judge: Hon. Peter J. Wilson
Department: CX102

STATEMENT OF DECISION

Trial Date: April 19, 2021
Sixth Am. Complaint filed: June 8, 2018
Case Filed: May 21, 2014

I. Introduction

This Court is aware of the toll being taken on society by what has been variously referred to as the "opioid crisis" or the "opioid epidemic." See, for example, *City and County of San Francisco v. Purdue Pharma L.P.* (N.D. Cal. 2020) 491 F.Supp.3d 610, 629. Drug abuse, including opioid abuse, affects not only the individuals directly involved, but their family and friends, doctors and other medical care providers, emergency rooms, law enforcement, and indeed all those impacted at each step of the drug-abuse cycle. Opioid-related hospitalization rates and opioid-related deaths starkly demonstrate the enormity of the ongoing problem.

Defendants do not dispute that there is an opioid crisis.

What Defendants dispute is whether the People have proven that the opioid crisis constitutes an actionable public nuisance for which Defendants, or any of them, are legally liable.

The Court's findings and conclusions address the question of liability based on the evidence in this trial, and are in no manner intended to ignore or minimize the existence and extent of the ongoing opioid crisis.

II. The Pleadings and Parties, Phase I Trial

The People commenced this action by filing their Complaint on May 21, 2014. Plaintiff is the People of the State of California, acting by and through Santa Clara County Counsel, Orange County District Attorney, Los Angeles County Counsel, and the Oakland City Attorney. The counties of Santa Clara, Orange and Los Angeles, and the City of Oakland are not parties to this action. (Santa Clara County, Orange County, Los Angeles County and the City of Oakland are together referred to as the "Jurisdictions.")

The operative complaint is the Sixth Amended Complaint filed June 8, 2018. The Sixth Amended Complaint asserts causes of action for False Advertising (Business and Professions Code sections 17500 *et seq.*), Unfair Competition (Business and Professions Code sections 17200 *et seq.*), and Public Nuisance (California Civil Code sections 3479 and 3480).

In summary, the People contend that each Defendant engaged in an aggressive false and/or misleading marketing scheme designed to increase, and which succeeded in increasing, the writing of prescriptions for Defendants' opioid medications, and that the increased prescriptions

have caused or contributed to the opioid crisis (defined more fully below) being experienced in California, including in the Jurisdictions. The opioid crisis constitutes the public nuisance which the People seek to abate in their third cause of action. The alleged false and/or misleading marketing constitutes the false advertising which forms the basis for the first and second causes of action.

Phase I of this case regarding liability was tried to the Court between April 19, 2021, and July 27, 2021. No party requested trial by jury on any claim or issue. The entire trial was conducted remotely, via the Zoom platform.

Defendants at trial were Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc. (collectively the "Janssen Defendants"), Endo Pharmaceuticals Inc., Endo Health Solutions Inc. (collectively the "Endo Defendants"), Allergan plc, Allergan Finance, LLC (collectively the "Allergan Defendants"),[1] Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC f/k/a Actavis Inc. (collectively the "Teva Defendants"), Actavis Pharma, Inc., and Watson Laboratories, Inc.[2]

The People rested their case in chief on June 2, 2021. Defendants thereafter filed motions for judgment pursuant to Cal. Code Civ. Proc. section 631.8. After full briefing on the motions, and oral argument, the Court declined to render judgment until the close of all the evidence in the case. Defendants then put on their respective cases, followed by the People's rebuttal.

The parties called witnesses and introduced various exhibits into evidence. Witness testimony was also introduced by written and videotaped depositions. The parties also stipulated to various facts, and party-admissions were admitted and read into the record.

All parties rested on July 27, 2021.

---

[1] Allergan plc is currently known as Allergan Limited and was formerly known as Actavis plc. Allergan Finance, LLC was formerly known as Actavis, Inc., which, in turn, was formerly known as Watson Pharmaceuticals, Inc. Therefore, as used herein, "Allergan plc" refers to the entity referenced in the Sixth Amended Complaint as "Actavis plc," and "Allergan Finance, LLC" refers to the entity referenced in the Sixth Amended Complaint as "Actavis, Inc.", "Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.", and "Watson Pharmaceuticals, Inc."

[2] Actavis Pharma, Inc., and Watson Laboratories, Inc. were dismissed with prejudice by the People after the People rested their case in chief.

All proceedings against named defendants Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company, Inc. have been stayed by reason of a bankruptcy filing.

The Court set a briefing schedule for closing briefs, and closing arguments were heard on September 30, 2021, and October 1, 2021.

Having received and considered the parties' respective briefs, having heard the closing arguments and having considered the evidence and the law, the Court issued its Tentative Decision on November 1, 2021. As directed by the Court, Defendants filed and served a [Proposed] Statement of Decision and a [Proposed] Judgment on November 23, 2021. On December 13, 2021 the People filed their Objections to the proposed statement of decision and to the proposed judgment. Having considered the proposed statement of decision and the proposed judgment, and the People's objections thereto, the Court now issues its Statement of Decision. The Judgment will be entered separately, simultaneously herewith.

There is no dispute that the burden of proof as to the allegations of the Sixth Amended Complaint is on the People, and that the People's burden is to be discharged by a preponderance of the evidence.

III. The Claims Asserted

A. First Cause of Action — False Advertising ("FAL")

Bus. & Prof. Code § 17500 provides, in relevant part, as follows:

> "It is unlawful for any person . . . corporation . . . or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state . . . in any newspaper or other publication, or any advertising device . . . or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . ."

And as relevant to the standing of the People to assert this claim, Bus. & Prof. Code § 17536 provides in relevant part that:

"(a) Any person who violates any provision of this chapter shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction."

B. Second Cause of Action — Unlawful Business Practices ("UCL")

Bus. & Prof. Code § 17200 provides, in relevant part, as follows:

"As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1."

Section 17206 provides in relevant part as follows:

"(a) Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General, by any district attorney, by any county counsel . . . ."

C. Third Cause of Action — Public Nuisance

Civil Code section 3479 provides, in relevant part, as follows:

"Anything which is injurious to health, including, but not limited to, the illegal sale of controlled substances, or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . is a nuisance."

Section 3480 provides as follows:

"A public nuisance is one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."

Section 3482 provides as follows:

"Nothing which is done or maintained under the express authority of a statute can be deemed a nuisance."

IV. Discussion and Findings

A. Public Nuisance

In *People v. ConAgra Grocery Products Co.* (2017) 17 Cal.App.5th 51, a case extensively relied upon by the People, the Court of Appeal set forth critical aspects of the law on public nuisance as follows:

> "A public nuisance cause of action is established by proof that a defendant knowingly created or assisted in the creation of a substantial and unreasonable interference with a public right. (*Santa Clara I, supra*, 137 Cal.App.4th at pp. 305-306, 40 Cal.Rptr.3d 313.)
>
> * * *
>
> "Causation is an element of a cause of action for public nuisance. (*Melton v. Boustred* (2010) 183 Cal.App.4th 521, 542, 107 Cal.Rptr.3d 481.) 'A connecting element to the prohibited harm must be shown.' (*In re Firearm Cases* (2005) 126 Cal.App.4th 959, 988, 24 Cal.Rptr.3d 659 (Firearm Cases).) The parties agree that the causation element of a public nuisance cause of action is satisfied if the conduct of a defendant is a substantial factor in bringing about the result. (*Citizens for Odor Nuisance Abatement v. City of San Diego* (2017) 8 Cal.App.5th 350, 359, 213 Cal.Rptr.3d 538 [applying substantial factor standard in a public nuisance action].) '"The substantial factor standard is a relatively broad one, requiring only that the contribution of the individual cause be more than negligible or theoretical." [Citation.] Thus, "a force which plays only an 'infinitesimal' or 'theoretical' part in bringing about injury, damage, or loss is not a substantial factor" [citation], but a very minor force that does cause harm is a substantial factor [citation].' (*Bockrath v. Aldrich*

Chemical Co., Inc. (1999) 21 Cal.4th 71, 79, 86 Cal.Rptr.2d 846, 980 P.2d 398.)

* * *

"""*Anything* which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . is a nuisance." (Civ. Code, § 3479, italics added.) "A *public* nuisance is one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal." (Civ. Code, § 3480[, italics added].) ... [¶] "*[P]ublic* nuisances are offenses against, or interferences with, the exercise of *rights common to the public*." (*People ex rel. Gallo v. Acuna* (1997) 14 Cal.4th 1090, 1103 [60 Cal.Rptr.2d 277, 929 P.2d 596], [first italics added].) "Of course, not every interference with collective social interests constitutes a public nuisance. To qualify, and thus be enjoinable [or abatable], the interference must be both *substantial* and *unreasonable*." ([*Id.* at p. 1105 [60 Cal.Rptr.2d 277, 929 P.2d 596]].) It is substantial if it causes significant harm and unreasonable if its social utility is outweighed by the gravity of the harm inflicted. ([*Ibid*].)' (*Santa Clara I, supra*, 137 Cal.App.4th at p. 305, 40 Cal.Rptr.3d 313.)"

ConAgra, 17 Cal.App.5th at 79, 101-102, 111-112.

1. Summary of Findings — Public Nuisance

There is no dispute that the "interference with collective social interests" caused by the abuse of opioids is "substantial."

Civil Code sections 3479, 3480 and 3482, and applicable case law, further require that the People prove (1) that one or more of the Defendants' alleged contribution to the interference was

"unreasonable" in that the social utility of the conduct constituting the interference is outweighed by the gravity of the harm inflicted, and (2) that the contribution of that Defendant was more than "negligible or theoretical." *Id.*

As explained more fully below, the People have failed to prove the element of "unreasonable" interference as defined in *ConAgra* and other cases. And, even assuming some unreasonable interference by one or more of Defendants, the People have failed to prove that any such alleged interference was more than "negligible or theoretical."

2. The People Have Failed to Prove The "Unreasonable" Element of Public Nuisance

As already noted, while there is some disagreement between the parties about a precise definition and scope, there is no dispute that there has been and continues to be an "opioid crisis" in the country, in California, and in the Jurisdictions. (The People define it as a "multifaceted opioid crisis." Proposed Statement of Decision 1:16. The Allergan Defendants note that "Opioid abuse is a significant societal problem." Post-Trial Brief 1:2. The Janssen Defendants note that "The abuse and misuse of opioids . . . are serious public-health issues that have disrupted lives and communities in California and elsewhere." Brief in Response 1:14-16. Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and Actavis LLC note the "California opioid epidemic." Post-Trial Brief 28:17, 26-27. And the Endo Defendants note the "opioid crisis." Proposed Statement of Decision 52:8.)

The evidence has shown, and the Court finds, that each of the Jurisdictions is dealing, to varying degrees, with an opioid crisis that includes Opioid Use Disorder ("addiction"), misuse, overdose and death.

The evidence further establishes all of the following:

1. All of Defendants' opioid products at issue here are Schedule II controlled substances under the Controlled Substances Act, 21 U.S.C. § 812. Schedule II drugs carry "a high potential for abuse" and can "lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2)(A), (C). (As stated in full: "(2) SCHEDULE II. (A) The drug or other substance has a high potential for abuse. (B) The drug or other

substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.")

2. There are patients for whom prescription opioids are medically appropriate.

3. A person can get addicted to opioids even if the person takes them as prescribed by their doctor.

4. There is a direct correlation between an increase in opioid prescriptions and the frequency of misuse, abuse, overdose, and drug related fatalities.

5. There is a direct correlation between increased dose and duration of opioid prescriptions and the frequency of misuse, abuse, overdose, and drug related fatalities.

6. The facts stated in paragraphs 1 through 5 above have at all material times been known to the Food and Drug Administration ("FDA") and each of the Defendants. The facts stated in paragraphs 1 and 2 have at all material times been known to the California Legislature.

As obviously follows from paragraph 1 above, the Federal government, through the FDA and the Drug Enforcement Administration ("DEA"), at all material times approved the Defendants' respective opioid medications, for their approved uses. It did so cognizant of the risks, but having made the determination that the benefits of these medications outweighed their risks. Stated differently, the Federal government made a determination that the "social utility" of appropriately prescribed opioids outweighed the "gravity of the harm inflicted" by them. *ConAgra*, 17 Cal.App.5th at 79, 111-112; *see* Ex. TE-CA-700884.0008 ("The statutory standard for FDA approval of a product is that the product is safe and effective for its labeled indications under its labeled conditions of use . . . . FDA's determination that a product is safe, however, does not suggest an absence of risk. Rather, a product is considered to be safe if the clinical significance and probability of its beneficial effects outweigh the likelihood and medical importance of its harmful or undesirable effects. In other words, a product is considered safe if it has an appropriate benefit-risk balance for the intended population and use. . . . Thus, assessment and comparison of a product's benefits and risks is a complicated process that is influenced by a

wide range of societal, healthcare, and individualized patient factors.") (Internal citations omitted.); *Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1063 ("But there is an important distinction between prescription drugs and other products . . . . In the latter cases, the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable.").

In turn, the California Legislature saw fit to ensure that opioid medications were available to patients who needed them. The California Legislature adopted a two-pronged approach. First, in passing the Intractable Pain Treatment Act (Business and Professions Code section 2241.5) in 1990 and in passing the Pain Patient's Bill of Rights in 1997, it ensured that health care practitioners could, in appropriate circumstances, prescribe opioid medications without risk of discipline. Second, in passing the Pain Patient's Bill of Rights in 1997, it ensured that pain patients would have access to opioid medications where that was medically appropriate.

The Pain Patient's Bill of Rights (Health and Safety Code section 124961, read with 124960), provides, in relevant part, as follows:

> "124961: Nothing in this section shall be construed to alter any of the provisions set forth in Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.
>
> (a) A patient who suffers from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.
>
> (b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve that pain without first having to submit to an invasive medical procedure . . . as long as the prescribing physician acts in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.
>
> (c) . . .
>
> (d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as

long as that prescribing is in conformance with Section 2241.5 of the Business and Professions Code."

Health & Safety Code section 124960 provides as follows:

"The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as

long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

Business and Professions Code Section 2241.5 provides, in relevant part, as follows:

"2241.5. Prescription or administration of dangerous drugs or prescription controlled substances for treatment of pain or condition causing pain

(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

(b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."

To avoid Federal preemption issues the People have stressed throughout that they are not asking this Court to sit in judgment of the FDA's approvals of prescription opioids. And, to avoid California safe harbor protections (in particular, Civil Code section 3482 which provides that nothing done under the express authority of a statute can be deemed a nuisance (*supra*)), the People have stressed that they are not asking this Court to find a public nuisance based on conduct expressly permitted by law.

Mindful of those limiting factors, the People nevertheless contend: that neither Federal nor California law precludes a finding of liability based on false or misleading marketing and promotion; that Defendants knew increased opioid prescriptions result in increased adverse downstream consequences; and that Defendants' false or misleading marketing and promotion in fact resulted in increased prescriptions, with increased adverse downstream consequences (the "opioid crisis" alleged).

Most significantly, the People also contend that they need only prove that the number (and/or the dose and duration) of prescriptions increased, without distinguishing between medically appropriate and medically inappropriate prescriptions.

The Court disagrees.

Specifically, the Court finds that even if any of the marketing which caused an increase in the number, dose or duration of opioid prescriptions *did* include false or misleading marketing, any adverse downstream consequences flowing from *medically appropriate* prescriptions cannot constitute an actionable public nuisance. This is so because, as the Federal government and the California Legislature have already determined, and as this Court finds, the social utility of medically appropriate prescriptions outweighs the gravity of the harm inflicted by them and so is not "unreasonable" or, therefore, enjoinable. *ConAgra*, 17 Cal.App.5th at 79, 111-112.

The People have shown that during the period 1997 (when the Pain Patient's Bill of Rights was passed) through 2011 the volume of opioid prescriptions (in both numbers and dosage) increased dramatically. But the mere proof of a rise in opioid prescriptions does not, without more, prove there was also a rise in medically *inappropriate* opioid prescriptions. The People made no effort to distinguish between medically appropriate and medically inappropriate prescriptions. There is simply no evidence to show that the rise in prescriptions was not the result of the medically appropriate provision of pain medications to patients in need. A need the Pain Patient's Bill of Rights and the Intractable Pain Treatment Act (Business and Professions Code section 2241.5) were specifically designed to meet.

The People proffered *no* evidence that the allegedly false or misleading marketing by Defendants caused the writing of medically inappropriate prescriptions. Instead, the People ask the Court to infer that the rise in prescriptions generally must logically also have resulted in the rise of medically inappropriate prescriptions. But there is no evidence, other than the rise itself, from which this Court can reasonably draw such an inference. And even if the Court could reasonably infer that false or misleading marketing must have caused *some* medically inappropriate prescriptions to be written, no evidence before the Court enables it to conclude, without rank speculation, whether the number or volume of such medically inappropriate prescriptions contributed to the alleged public nuisance, and if so, to what extent. The People have themselves (in argument and through their expert witness Dr. David Herzberg) described the opioid crisis as multifaceted, with contributing actors including manufacturers, distributors,

pharmacies, doctors, the illegal drug trade, the FDA, the DEA, and the State of California. While the People are not required to prove the exact contribution of each of these contributing actors, including of each Defendant, they must nevertheless prove that the contribution of each Defendant was more than "negligible or theoretical." *ConAgra*, 17 Cal.App.5th at 79, 102.

Here, with no evidence to identify the existence or volume of medically inappropriate opioid prescriptions caused by Defendants' allegedly improper marketing, determining whether such cause was "negligible or theoretical" (insufficient to establish causation), or minor (sufficient to establish causation) in relation to the overall opioid crisis, would require wholly unsupported speculation.

Instead, the People's evidence undermines their own case. The People's evidence shows that, as everybody knew, as the number, dose and duration of prescriptions increase, so too do the adverse downstream consequences. But this does not assist the People's case. The FDA knew about the risks of opioids; that is precisely why the FDA designated opioids as Schedule II drugs. The FDA continues to approve these drugs for use where medically appropriate. And when the FDA was requested in 2013, at a time when the opioid crisis was already full blown, to impose dose or duration limits, the FDA declined to do so, leaving such decisions instead to the healthcare practitioner in consultation with his or her patient.

And as already noted, the California Legislature has approved, and continues to approve, the availability of opioid medications, through prescriptions, by passing the laws described above.

As the Historical and Statutory Notes to Business & Professions Code section 2241.5 state, "it is the intent of the Legislature to encourage physicians to provide adequate pain management to patients in California consistent with Section 2241.5." And the California Legislature made clear its intention to expand, rather than restrict, the appropriate prescribing of opioid medications. In 1990 section 2241.5 provided for the prescribing or administering of controlled substances "for a diagnosed condition *causing intractable pain*." (Emphasis added.) That language was repeated in a revised version of section 2241.5 in 2004. Effective January 1, 2007 the section was amended to read as follows: "A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition

dangerous drugs or prescription controlled substances for the treatment of pain *or a condition causing pain, including, but not limited to, intractable pain.*" (Emphasis added.) And subsection (b) was revised to read straightforwardly as follows: "No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section." (This replaced former subsection (c) which had referenced intractable pain.)

As cited in *ConAgra*, "'"[o]f course, not every interference with collective social interests constitutes a public nuisance. To qualify, and thus be enjoinable [or abatable], the interference must be both *substantial* and *unreasonable*." (Citation omitted.) It is substantial if it causes significant harm and unreasonable if its social utility is outweighed by the gravity of the harm inflicted. ([*Ibid*].)' (*Santa Clara I*, supra, 137 Cal.App.4th at p. 305, 40 Cal.Rptr.3d 313.)" *ConAgra*, 17 Cal.App.5th at 112.

Regardless how the opioid crisis is defined, it is without question *substantial*.

But with no evidence to demonstrate or suggest that the increased prescriptions were not medically appropriate, and with no evidence that even attempts to quantify how medically inappropriate prescriptions caused or contributed to the opioid crisis, the People have failed to demonstrate that the interference by Defendants, or any of them, was *unreasonable*. If every prescription was medically appropriate for that patient, the highly regrettable but foreseeable adverse downstream consequences are not unreasonable as that term is used in *ConAgra* (and the cases it cites). Under the People's own theory and evidence, as medically appropriate prescriptions continue to be written, adverse downstream consequences will inevitably continue to occur, as the entirely foreseeable consequence of the continued approval of opioids by both the Federal government and the California Legislature.

The People rely extensively on *ConAgra*, in support of their theories generally and specifically in support of their arguments concerning aggregate proof as it relates to causation. But *ConAgra* dealt with a product, lead paint, that had no appropriate indoor use and therefore there was no reason for the court there to distinguish between marketing and promotion resulting in proper versus improper uses.

State ex rel. Wilson v. Superior Court (2014) 227 Cal.App.4th 579, also relied upon by the People, in fact shows the fallacy in their argument that aggregate proof (at least in the form presented here) is somehow always sufficient. There, the Court of Appeal reversed a trial court's order granting summary adjudication, finding that on the facts and issues presented there, the trial court had incorrectly concluded that "proof of causation must be on a prescription-by-prescription and claim-by-claim basis." In holding that "causation may in many instances be inferred from evidence that does not itself constitute direct evidence of reliance on an individual basis" the Court of Appeal went on to hold that of course actual evidence would still be necessary and theorized: "In the underlying case, such evidence might, for example, show that the individuals influencing or controlling the choice of drugs available for prescription in a particular hospital or other formulary had specified a preference for a BMS drug, to the exclusion of equally appropriate drugs of its competitors, only after being provided substantial unearned benefits by BMS. The prescription of BMS drugs under such a regimen might tend to show that the BMS prescriptions and claims resulted more from the benefits provided than from individual treatment decisions. (We do not suggest by this example that any such evidence exists or would necessarily be persuasive or controlling.)" *Id.* at 608.

That is precisely the point here. The People could have shown, or at least attempted to show, that Defendants' marketing and promotion caused health care providers to write medically inappropriate prescriptions. The People could have shown, or at least attempted to show, singly or in the aggregate how many medically inappropriate opioid prescriptions were written, and the correlation between those numbers, and/or the increase in those numbers, and Defendants' marketing efforts. The Court will not opine on all the ways in which the People could have sought to discharge their burden, but the People sought to introduce no such evidence.

The People rely on *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51. That case discusses in some detail inferences that can properly be drawn about the connection between overpromotion and subsequent prescriptions. *Stevens* also, however, stresses a very salient point. The Supreme Court there highlights the essential fact that the overpromotion could be inferred to have caused the physician to prescribe the drug "when not justified." *Id.* at 66, 68. Specifically, the Court

held: "It is reasonable to assume that the company's efforts consciously or subconsciously influenced [the physician]. In addition, plaintiff introduced expert testimony by a physician that the advertising and promotion of the drug 'played a role' in inducing physicians to prescribe it *when it was not sound practice to do so*." *Id.* at 68. (Italics added.)

Here, the People's experts simply opined that Defendants knew, or must have known, that as the gross number of prescriptions increased, and/or the dose and duration of prescriptions increased, so did the risks of diversion and/or abuse. Again, at the risk of repetition, in the context presented here the Court cannot conclude that the increase in medically appropriate prescriptions can be a basis for public nuisance liability, even if undesirable consequences follow.

3. The People Have Failed to Prove Causation

In addition to its relevance to proof of the "unreasonableness" element of a public nuisance claim as discussed above, the absence of evidence concerning medically inappropriate prescriptions also breaks the chain of causation between Defendants' alleged wrongful conduct and the harms complained of. In *In re Firearm* Cases (2005) 126 Cal.App.4th 959, the Court of Appeal stressed that causation is "a necessary element of a public nuisance claim." After citing to the Restatement Second of Torts, the Court held as follows:

> "This listing of examples of public nuisance illustrates the need for a relationship between the conduct and the impending harm."
>
> "In this case, there is no causal connection between any conduct of the defendants and any incident of illegal acquisition of firearms or criminal acts or accidental injury by a firearm."
>
> *Id.* at 987, 989.

Here, there is no evidence of medically inappropriate prescriptions caused or induced by any allegedly false or misleading marketing and promotion by Defendants, and the conclusion of the Court of Appeal is entirely apposite:

> "Plaintiffs' public nuisance claim fails for lack of any evidence of causation. Their complaint attempts to reach too far back in the chain of distribution when it targets

> the manufacturer of a legal, non-defective product that lawfully distributes its product only to those buyers licensed by the federal government.
>
> We do not hold that the theories asserted would never be tenable under different evidence. We merely find, based on the evidence presented here, that the evidence does not sufficiently establish the alleged acts of the defendants caused the diversion of firearms *to the criminal market*."

Id. at 991-92. (Emphasis added.)

While the Court recognizes that the People here contend that Defendants did not "lawfully distribute" their products because they were using allegedly false or misleading marketing and promotion, that does not change the essential fact that there is no evidence supporting a causal connection between the alleged conduct and adverse downstream consequences flowing from medically *inappropriate* prescriptions. ("In this case, there is no causal connection between any conduct of the defendants and any incident of illegal acquisition of firearms or criminal acts or accidental injury by a firearm." *In re Firearm Cases*, 126 Cal.App.4th at 989.)

None of the arguably analogous public nuisance cases dictates a different result.

In *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, the alleged public nuisance was the existence of lead paint in homes, buildings and other property. In terms similar to some of those alleged here, the Court of Appeal held as follows:

> "Here, Santa Clara, S.F., and Oakland alleged that defendants assisted in the creation of this nuisance by concealing the dangers of lead, mounting a campaign against regulation of lead, and promoting lead paint for interior use even though defendants had known for nearly a century that such a use of lead paint was hazardous to human beings. Defendants '[e]ngag[ed] in a massive campaign to promote the use of lead on the interiors and exteriors of private residences and public and private buildings and for use on furniture and toys.' Had defendants not done so, lead paint would not have been incorporated into the interiors of such a large number of buildings and would not have created the enormous public health hazard that now exists. Santa Clara, S.F., and

Oakland have adequately alleged that defendants are liable for the abatement of this public nuisance."

Id. at 306.

If the similarities to the present case are obvious, so are the distinctions. The FDA approves the use of opioids in appropriate circumstances, and the California Legislature approves and promotes the use of opioids in appropriate circumstances. The Court must accordingly draw a distinction between conduct resulting in the anticipated, approved use, and conduct resulting in improper use. The evidence does not permit the Court here to draw (and measure) that distinction.

City of Modesto Redevelopment Agency v. Superior Court (2004) 119 Cal.App.4th 28 involved, among other things, claims that the defendant instructed users to dispose of certain hazardous chemicals into drains and sewers. The court there had no occasion to determine appropriate versus inappropriate discharge. On the facts alleged *any* discharge into drains and sewers was potentially problematic. (The Court of appeal was addressing these issues in the context of demurrers and motions for summary adjudication, not after trial.)

In *People ex rel. Gallo v. Acuna* (1997) 14 Cal.4th 1090, the California Supreme Court, in upholding an order enjoining certain gang behavior, carefully examined whether the enjoined behavior improperly included "constitutionally protected associational interests." The Court there found that in the area covered by the injunction, the gangs "appeare[d] to have had no constitutionally protected or even lawful goals . . . . So far as the record before the trial court shows, the gangs and their members engaged in no expressive or speech-related activities which were not either criminally or civilly unlawful or inextricably intertwined with unlawful conduct." *Id.* at 1119, 1121. Here, it is indisputable that the opioid prescriptions included entirely lawful medically appropriate prescriptions. And no evidence establishes the existence, volume and/or number of medically inappropriate prescriptions.

Accordingly, on the basis of the evidence presented here, the Court finds that the People have failed to prove an actionable public nuisance for which Defendants, or any of them, are legally liable.

Nothing stated herein is intended to suggest that false or misleading marketing and promotion that results in medically inappropriate prescriptions being written may not constitute an actionable public nuisance. But that is not the evidence before this Court.

The Court declines to rule on the allegedly false or misleading statements in any of the materials falling outside of the limitations periods applicable to the FAL or UCL claims, as they are not relevant to the Court's decision.

B. The False Advertising and Unfair Competition Law Claims

"California's false advertising law (§ 17500 *et seq.*) makes it 'unlawful for any person, . . . corporation . . . , or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate . . . before the public in this state, . . . in any newspaper or other publication . . . or in any other manner or means whatever . . . any statement, concerning that real or personal property or those services . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . .' (§ 17500.) Violation of this provision is a misdemeanor. (*Ibid.*) As with the UCL, an action for violation of the false advertising law may be brought either by a public prosecutor or by 'any person acting for the interests of itself, its members or the general public,' and the remedies available to a successful private plaintiff include restitution and injunctive relief. (§ 17535.)

"This court has recognized that '[a]ny violation of the false advertising law . . . necessarily violates' the UCL. (*Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 210, 197 Cal.Rptr. 783, 673 P.2d 660.) We have also recognized that these laws prohibit 'not only advertising which is false, but also advertising which [,] although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public.' (*Leoni v. State Bar* (1985) 39 Cal.3d 609, 626, 217 Cal.Rptr. 423, 704 P.2d 183.) Thus, to state a claim under either the UCL or the false advertising law, based on false advertising or promotional practices, 'it

is necessary only to show that "members of the public are likely to be deceived."'" (Citations omitted.)

Kasky v. Nike, Inc. (2002) 27 Cal.4th 939, 950, *as modified* (May 22, 2002).

An important issue arising from the statute, and the cases interpreting it, is that the statements complained of must have been "ma[de] or disseminate[d] . . . before the public," here, in particular, health care providers and patients. Indeed, Part 3 of the Business and Professions Code, which commences with section 17500, is entitled "Representations to the Public." Thus, an allegedly false or misleading statement in an internal company document, that was in no way published or disseminated before the public, would not qualify as "false advertising" under the statute or applicable cases.

In addition to the FAL, the People assert UCL liability based on alleged violations of the Sherman Food, Drug, and Cosmetic Laws as well as the CLRA. Regarding both those statutes, the People make the same allegations concerning the allegedly false or misleading nature of Defendants' marketing and promotion. Proposed Statement of Decision, para. 763. Regarding allegations of fraudulent business practices under the UCL, the People allege that each Defendant violated the "fraudulent" prong "by marketing and promoting their opioids in California in a false and misleading manner that was likely to deceive healthcare providers and the public." Proposed Statement of Decision, para. 764(a).

There is no dispute as to the applicable limitations periods for the FAL and UCL claims. They are as follows.

FAL: From and after May 21, 2011 with respect to the Janssen Defendants, the Allergan Defendants, and the Endo Defendants; From and after March 23, 2015 with respect to the Teva Defendants.

UCL: From and after May 21, 2010 with respect to the Janssen Defendants, the Allergan Defendants, and the Endo Defendants; From and after March 23, 2014 with respect to the Teva Defendants.

Regarding internal documents that were used in the training of sales representatives, but not themselves "published," the Court draws the reasonable inference that the sales

representatives would have relied on such documents in their doctor visits.

What is more problematic is to determine whether the Court can identify, without simply speculating, precisely what statements in those documents were repeated by sales representatives to anyone they called on. This problem has two components.

First, there are documents where the People do not rely on the actual words in the document, but rather argue about what the words used must mean. Thus the Court must attempt to determine what was said, before making a determination as to whether what was said amounted to a false or misleading statement.

And second, there are documents where allegedly false statements appear alongside much other information, and the Court must decide whether the People have proven that the false statements, and not the other information, were communicated.

For all statements relied on, the People must prove that they were likely to deceive the recipient. *In re Tobacco II Cases* (2009) 46 Cal.4th 298, 312. And, "[w]here the advertising or practice is targeted to a particular group or type of consumers, either more sophisticated or less sophisticated than the ordinary consumer, the question whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily directed." *In re Vioxx Class Cases* (2009) 180 Cal.App.4th 116, 129. the People must prove "that a significant portion of the . . . targeted consumers, acting reasonably in the circumstances, could be misled." *Ebner v. Fresh, Inc.* (9th Cir. 2016) 838 F.3d 958, 965 (emphasis added) (quoting *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496). A "mere possibility" that marketing "might conceivably be misunderstood" by "unreasonable" consumers cannot support an FAL claim. *Id.*

Whether a statement is misleading must be considered "in the context of the entire document." *Freeman v. Time, Inc.* (9th Cir. 1995) 68 F.3d 285, 290.

Further, courts have held that FAL liability arises only from "specific rather than general assertions." *Newcal Indus., Inc. v. Ikon Off. Sol.* (9th Cir. 2008) 513 F.3d 1038, 1053; *accord Demetriades v. Yelp, Inc.* (2014) 228 Cal.App.4th 294, 311. That is, "a general, subjective claim about a product is non-actionable puffery" because it is "extremely unlikely to induce consumer

reliance." *Newcal Indus.*, 513 F.3d at 1053.

Finally, advertising that takes a legitimate position on matters of scientific debate cannot be false and misleading, as "[t]he UCL, FAL, and CLRA do not requir[e] unanimous scientific consensus for each advertising claim on Defendants' products." *Reed v. NBTY, Inc.* (C.D. Cal. Nov. 18, 2014, No. EDCV 13-0142 JGB (OPx)) 2014 WL 12284044, at *14 (applying California law).

Applying these principles, the Court's findings concerning the false or misleading statements relied upon by the People are as stated below. Given the repetitive nature of the Court's findings, the Court does not attempt to explain its findings at length for each document.

1. Janssen Defendants

The Janssen Appendix identifies 17 documents as containing false or misleading statements. Of those, only 7 are shown to have been used in any manner during the applicable limitations periods for the FAL (May 21, 2011) and UCL (May 21, 2010) claims. The undated document Risk Management (REMS) for Tapentadol ER (P-CA-000658) is included in the 7, because the footnotes identify data from 2011, thus giving the document a date of 2011 or later. In Ex. JAN-CA-601318, only pages .00015, .00016 and .00017 potentially could fall within the limitations periods. For all other documents, nothing in the documents, or in any testimony concerning them, establishes that they were used or referenced in any way during the limitations periods.

The Court addresses the documents in the sequence in which they are cited in the Janssen Appendix.

Sales Training for Nucynta and Nucynta ER (P-CA- 001787)

The People identify as false or misleading a statement on page .020 of this thirty-one page document. The Court finds nothing false or misleading in the reference to "Moderate to SEVERE chronic pain." At p. .005, the document states that "NUCYNTA ER is indicated for the management of moderate to severe *chronic* pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." That was the FDA approved use. As will be repeated often herein in relation to many of the documents relied on by the People, it is

not a valid criticism that every single page of a document does not contain all of the information set forth in all of the other pages of the document. Any document must be viewed as a whole, to determine whether in the context of the entire document, some part thereof is false or misleading in a material way. The complained of statement is not in context false or misleading, and there is no evidence to show, nor to support a reasonable inference, that a sales representative, based on this document, falsely or misleadingly misrepresented the appropriate use of the medication.

Risk Management (REMS) for Tapentadol ER (P-CA-000658)

The People identify as false or misleading statements on page .0018 of this thirty-nine page document. The People's characterization of the statements is inconsistent with the statements themselves, and again ignores context. Much of the document is devoted to explicit explanations of the risks of opioids. The document notes that the REMS programs are designed to mitigate serious risks associated with particular drugs. The document discusses misuse, abuse, and diversion, shows the rate of unintentional drug overdose deaths in the United States, and distinguishes addiction from dependence. In the context of patients who become physically dependent, but not addicted, the statement is made "once opioid treatment is no longer needed, patients are able to discontinue opioid use without difficulty, provided the dosage is tapered gradually." Based on the evidence presented, the Court does not find this statement false or misleading. To the extent that not all doctors appear to agree as to the ease or difficulty of tapering in a physically dependent, but not addicted, patient, this professional disagreement does not render the statements actionably false or misleading. The Court also does not find the reference to risk assessment tools and procedures false or misleading. The evidence presented confirmed the value of such tools and procedures in opioid prescribing.

NUCYNTA® ER Frequently Asked Questions (FAQs) (P-CA-000579)

The People identify 6 allegedly false or misleading statements in this twenty-six page document. Read in the context of the entire document, the Court finds none of the identified statements to be false or misleading. In the scripted questions and answers, the information includes that "NUCYNTA® ER was not designed to produce rapid onset for the treatment of acute pain, rather it is designed to manage chronic pain over an extended period of time" (.0003),

the health care provider is to be given the "full Prescribing Information" (.0005), in determining dosage the health care provider is advised that "close observation and titration are indicated until a satisfactory dose is obtained on the new therapy" (.0007) and that "Treatment should be individualized for the patient and clinical judgment should be used to guide dosing and titration." (.0007). The information includes that "NUCYNTA® ER is indicated for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." (.0013). This is the FDA approved use for the product. Consistent with FDA guidance, the document notes that the Nucynta ER formulation was "designed to not be amenable to splitting, crushing or dissolution." (.0016). It does not claim that it is effective in achieving this result, and indeed states "Like all long-acting opioids, there is no postmarketing experience with NUCYNTA® ER tablets to assess whether the formulation deters abuse, misuse, or diversion." (.0016). Further, "Keep in mind, NUCYNTA® ER is a Schedule II controlled substance and can be abused in a manner similar to other opioid agonists." (.0017). In the context of the entire document, and based on the evidence at trial, none of the challenged statements are simply untrue, and none are false or misleading in the context presented.

Nucynta ER Launch Readiness (P-CA-000578)

The People identify 10 allegedly false or misleading statements in this forty-seven page document. Read in the context of the entire document, the Court finds none of the identified statements to be false or misleading.

The People identify as false or misleading any statement that can be interpreted as saying that a particular opioid product improves function. While the Court recognizes that the FDA has on occasion announced a concern that claims about improved function should not be made absent scientific evidence, the Court is persuaded based on the evidence in this trial that effective pain management and improved, or improvements in, function are closely linked concepts. It seems beyond debate that for a patient whose pain has been sufficiently controlled that they are able to resume some of the basic functions of life -shopping, cooking, cleaning, and so on – that patient's function has improved. Accordingly, where the statements complained of cannot reasonably be

interpreted as suggesting more than this basic definition of improved function, they are not false or misleading.

At .0005, the document describes that Nucynta ER is "[f]or the management of moderate to severe chronic pain in patients 18 years of age or older, when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." At .0031, the document provides that the Nucynta ER REMS program will be "mail[ed] to HCPs 3 weeks prior to product availability in retail pharmacy" and that the goals are "[t]o inform patients and healthcare professionals about the: [p]otential for abuse, misuse and addiction to NUCYNTA ER" and concerning the "[s]afe use of Nucynta ER."

More fundamentally, no evidence establishes or suggests that this document was used to train sales associates or that the contents of this document were in any other way communicated to persons outside the company.

A recurring issue with almost all the documents identified by the People as containing false or misleading messages is the extent to which the Court is being asked to infer what parts of the documents were presented to health care professionals, and in what manner. The only testimony on this subject was through deposition extracts from sales representatives, introduced by Defendants, all of whom testified that that they had scrupulously stayed within product labels in what they presented. The People persuasively argue that all of the training materials must have played a role in what the sales representatives ultimately conveyed to the healthcare providers. However, that argument does not account for internal non-training materials. And, for training materials, given the mix of medically appropriate information with the allegedly inappropriate information, and the significant absence of evidence about how any of the information was actually conveyed, inference necessarily becomes speculation as to what was actually conveyed.

DURAGESIC Journal Advertising Overview, March 1991-Present (JAN-CA-601318)

The People identify 5 allegedly false or misleading statements in the 3 documents in this exhibit which potentially could fall within the limitations period (.00015, .00016 and .00017). In the context of opioid medications, these documents can certainly be characterized as overoptimistic in their visual and verbal presentation. It is a closer call whether they can properly

be characterized as false and/or misleading. The Journal advertisements appear aimed at patients, although they would also be available to healthcare providers. On balance, because as directed to patients, these advertisements could only have prompted patients to seek opioids from their doctor (as opposed to directly buying them themselves), and as directed to healthcare providers, the context would have been readily understood, the Court finds none of the identified statements to be false or misleading. In reaching this conclusion, the Court also takes account of the testimony by the People's expert witness, Doctor Matthew Perri, that in his review of Janssen's marketing materials, he "found that the claims in Janssen's marketing materials track the FDA-approved labels fairly consistently" (Tr. 2245: 2-6) and he "did not see any indication of Janssen failing to include important safety information in its marketing pieces." Tr. 2252: 16-20.

NUCYNTA/NUCYNTA® ER Speakers' Slide Decks titled "New Perspectives in the Management of Moderate to Severe Chronic Pain" (P-CA-01793)

The People identify 4 allegedly false or misleading statements in this sixty-one page document. Read in the context of the entire document, the Court finds none of the identified statements to be false or misleading. As with earlier documents, it is not a valid criticism that all information from the entire document must be contained on every page. Every statement must be read in context. While page .003 has the heading "NEW PERSPECTIVES IN THE MANAGEMENT OF MODERATE TO SEVERE CHRONIC PAIN," page .005 sets forth the full indication for NUCYNTA , on the one hand, and NUCYNTA® ER, on the other. On the page bearing the heading "NUCYNTA® ER: LOW INCIDENCE OF OPIOID WITHDRAWAL SYMPTOMS" (.033), data is cited from clinical studies, with the summary "There were 635 subjects in the NUCYNTA® ER group assessed between Day 2 and Day 4 after abrupt cessation of treatment with 12% and 2% of subjects having mild or moderate withdrawal, respectively" and the further statement "Withdrawal symptoms may be reduced by tapering NUCYNTA® ER." (.033). That same page noted, in bold print, "Please see full Prescribing Information, including Boxed WARNING, available at this event." Page .038 commenced with "Risk Evaluation and Mitigation Strategy (REMS)" that was followed by 10 pages of "IMPORTANT SAFETY INFORMATION."

Keith Candiotti, MD "Use of Opioid Analgesics in Pain Management" (JAN-CA-600078)

The People identify 5 allegedly false or misleading statements in this article. The article sets forth the author's opinions, supported, where applicable, by citations to various studies, including studies relied upon by the various expert witnesses in this case. Read in the context of the entire document, the Court finds none of the identified statements to be false or misleading. the People's expert witness on marketing, Doctor Matthew Perri, identified this document as one showing Janssen's promotion of its products, but otherwise offered no opinions concerning the contents. No other witness testified to the content of this document. None of the criticisms of this document, which essentially asked the Court to determine whether the document provides sound medical advice, identify statements which can be characterized as false or misleading for FAL or UCL purposes.

2. Allergan Defendants and Actavis LLC

The Allergan Appendix identifies 21 documents as containing false or misleading statements. Of those, 14 are dated within the applicable limitations periods for the FAL (May 21, 2011) and UCL (May 21, 2010) claims. For all other documents, nothing in the documents, or in any testimony concerning them, establishes that they were used or referenced in any way during the limitations periods.

The Court addresses the documents in the sequence in which they are cited in the Allergan Appendix.

Kadian Learning System (P-CA-000251.003 - .194)

Although the Appendix identifies three versions of the Kadian Learning System, the Court addresses only the 2010 version (and thus rows 1, 3, 5 through 11, 13, and 15 through 18), as no evidence establishes that the earlier versions were used or relied upon during the relevant limitations periods. Where the People reference an earlier version, and the same or substantially similar language appears in the 2010 version, it is included in the rows identified.

As with some of the documents discussed earlier, this 192-page document requires a double inference. The first inference, which the Court reasonably draws based upon the intended

purpose of this document, is as follows: The information in this document was provided to salespeople so that they could communicate information to the healthcare providers on whom they called, and information from this document was in fact communicated to healthcare providers. The second, more problematic, inference involves determining whether what was actually conveyed by the salespeople contained false or misleading information. Because the Court concludes that none of the statements complained of contained a blatant falsehood or inaccuracy, the Court further concludes that it cannot reasonably draw the inference that information from this document was necessarily communicated to healthcare providers in a false or misleading manner.

The 192-page document comprises nine chapters, including Chapter 5 on "Drug Abuse and Chronic Pain," and in Chapter 6 a section on "Addiction Dependence, and Tolerance." Chapter 9 is entitled "Safety and Adverse Experiences." The black box FDA approved labeling for Kadian is set forth under the heading "FDA Safety Warnings for Kadian" (at pages .166 - 169). Reviewing the document as a whole, the Court agrees with the assessment of Dr. Carol Warfield that the document does not improperly minimize risks. Regarding specific statements alleged, the Court finds none of them to be false or misleading in the context of the document as a whole. Where the People challenge not the words used, but their meaning or import, the Court cannot speculate as to how that might have been conveyed to a healthcare provider.

Regarding "function," the Court has addressed that issue above.

Regarding "pseudoaddiction," this is a medically recognized term, describing a condition where a patient seeking more or stronger opioid medication might be doing so because their pain is undertreated, and not because they have or are developing an abuse disorder. The California Legislature itself recognized this condition, without using the term "pseudoaddiction," in Health and Safety Code section 11156(b)(2): "[A] person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section."

Regarding "no ceiling dose," this is a medically accurate statement and nothing in the document states or suggests that a healthcare provider should interpret "no ceiling dose" to mean that they can increase the dosage indefinitely. Instead, the Kadian Learning System states:

"Doses are titrated to pain relief, and so no ceiling can be given as to the recommended maximal dose especially in patients with chronic pain of malignancy. In such cases, the total dose of KADIAN® should be advanced until the desired therapeutic endpoint is reached or clinically significant opioid-related adverse reactions occur." (.164). The section is immediately followed by "Information for Patients" and the Black Box FDA warnings.

Regarding "addiction is rare": The document does not state that addiction is rare. Rather, the People identify various statements which they contend are intended to convey that addiction is rare. First, the Court is left to speculate as to precisely what information was actually imparted to healthcare providers. Without any evidence on that issue, the Court cannot determine whether such information was false or misleading. Second, to the extent that the document states that addiction is not commonplace, it is accurate, based on the testimony in this trial. The People identify the following allegedly false or misleading statement: "Clinicians who had been incorrectly trained to believe that taking opioids for a prolonged period would always result in addiction were surprised that most of these patients never exhibited any signs or symptoms of addictive disease." (.085). That statement appears in a section on "Substance Abuse and Chronic Pain" which provides a summary opioid use chronology, and concludes by stating: "The responsibility for knowing state and federal regulations regarding prescribing, dispensing, or administering controlled substances ultimately lies with the clinician. However, the Federation of State Medical Boards specifically states that clinicians should not fear disciplinary action for ordering, prescribing, or administering controlled substances for a legitimate medical purpose in the course of professional practice. Prescribing and administering controlled substances for pain are legitimate if prescribed for a medical purpose. Prescribing should be done in the context of a diagnosis and documentation of unrelieved pain as part of a physician-patient relationship. (Federation of State Medical Boards 2004)." (.086). Dr. Lembke testified that one in four patients prescribed opioids would become addicted. As Defendants point out, the studies relied upon by Dr. Lembke for that conclusion are inadequate to support it. The more reliable data would suggest less than 5%, rather than 25%. Under either number, addiction based solely on the patient having been prescribed opioids does not occur in "most of these patients."

Most fundamentally, the Court has no evidence of statements actually made to healthcare providers, or anyone else, based on this document. Given the very significant amount of information contained in the document, the Court cannot speculate as to what a salesperson chose to convey, or in precisely what manner. Absent such evidence, the Court cannot make a determination whether false or misleading information was actually published, as required for FAL or UCL liability.

Putting it All Together-2011 Kadian National Sales Meeting Slideshow by Jennifer Altier (P-CA-000265)

The challenged statement does not "claim there is no dose of opioids too high for the treatment of chronic non-cancer pain" and does not "state there is no ceiling dose for opioids without noting that the risks of addiction, overdose, and death increase with dosage." It is accurate that there is no maximum dose for Kadian, as demonstrated by the Kadian label. The February 2009 FDA-approved Kadian label, for example, stated that "No guidance can be given as to the recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN® should be advanced until the desired therapeutic endpoint is reached or clinically significant opioid-related adverse reactions intervene." (AL-CA-300275.00021.) Further, the referenced statements are in an email with an 85-page attachment, which includes the following information: "There is growing public safety concern regarding the use of long-acting opioid products . . . Concern over the increase in adverse events associated with LAOs, including improper dosing, indication and patient selection, as well as abuse and addiction, has led the FDA to request sponsors of certain opioids to develop a Risk Evaluation and Mitigation Strategy or 'REMS.' . . . The goal of REMS programs is to ensure that the benefits of the drugs continue to outweigh the risks associated with use of LAO" (.009).

July 2011 Sales Training Class - Introduction of Oxymorphone Hydrochloride Extended-Release Tablets CII (P-CA-001813)

Nothing in the challenged statement is shown to be inaccurate (it is essentially a statement about product availability and dosage strength for a generic) and the document discusses indications and usage, and contains the boxed warnings for the product.

Kadian Prescriber Research (P-CA-001645)

As the document makes clear, it is a "summary report from prescriber research" based on telephone interviews with prescribers. (See p. .001 read with .003.) The challenged statements do not represent statements attributable to any Allergan Defendant (or any other defendant in this case).

Kadian Marketing Overview-Sales Representative Training (AL-CA-300050); Objection Handling Messaging (July 13, 2011) and Kadian Promotional Training Slides October 2011) (P-CA-000128); 2011 Kadian Training Meeting - Managed Markets (P-CA-000079); Regional Meetings November 2011 Generic Kadian Sales Team Meeting (P-CA-000013); Email from Jennifer Altier attaching the approved generic Kadian telescript (P-CA-000065); Kadian Marketing Overview- Sales Representation Training (P-CA-000127); Kadian New Strengths Launch (P-CA-000045)

The Court finds nothing false or misleading in the statements cited from these documents.

Kadian Comparison Detailer (AL-CA-300114); Behind the Scenes: The Kadian Capsules Story — Promotional Piece (P-CA-001708); "When you can prescribe the benefits of Kadian capsules" detail piece (P-CA-001707); Kadian Co-Pay Assistance Program Brochure (AL-CA-300075); Kadian Sales Aid (P-CA-001706); Kadian Reprint, "Effect of Concomitant of Ingestion of Alcohol on the In Vivo Pharmacokinetics of Kadian" from the Journal of Pain (P-CA-001725); Kadian Conversion Guide Sales Aid (P-CA-001727)

As the People note, these documents were not distributed after February 2010. They accordingly fall outside the applicable limitations periods.

Kadian Dosing strengths brochure (P-CA-001718); Kadian Dosing Guide (P-CA-001709); Generic is Now Available - Oxymorphone Hydrochloride Extended-Release Tablets (P-CA-000070).

The Court finds nothing false or misleading in the statements cited from these documents.

///

///

3. Endo Defendants

The Endo Appendix identifies 11 documents as containing false or misleading statements. Of those, 4 are dated within the applicable limitations periods for the FAL (May 21, 2011) and UCL (May 21, 2010) claims. One is dated earlier, but the Endo Defendants concede its use during the UCL limitations period. For all other documents, nothing in the documents, or in any testimony concerning them, establishes that they were used or referenced in any way during the limitations periods.

The Court addresses the documents in the sequence in which they are cited in the Endo Appendix.

Opana ER Opioid Analgesics Overview: Product Therapeutic and Learning System (P-CA-000417)

The Court finds nothing false or misleading in this 63-page document, as a whole or in the statements cited from this document. In the Introduction the document states "However, the remarkable utility of opioids for pain relief and their unquestionable benefits in alleviating patient suffering are counter-balanced by the serious consequences of their misuse and abuse. As a Sales Representative working in the field of pain management, it is important for you to be aware of both these perspectives when working with this drug class and speaking with health care providers. Risk management with opioids will be discussed at length in the next module."

Opana ER Detail Aid (P-CA-000406)

The Court finds nothing false or misleading in this document. The People do not challenge particular words or statements as false or misleading, instead arguing for a misleading interpretation. That the product was "designed to be crush resistant" is consistent with the FDA's directions for the marketing of the product.

Letter from Endo to Julie Suko, decision-maker for "medication division support organization," regarding Reformulated Opana ER (P-CA-000507)

There is no evidence identifying the addressee of this letter, no evidence that the letter was actually sent, and no evidence that the letter was sent to or received by any person in California. It is accordingly not relevant to either the FAL claim or the UCL claim.

What you should know about treating your pain with opioids (P-CA-00416) (Incorrectly cited as DEF-CA-101950)

The Court finds nothing false or misleading in the statement cited from this document.

Responsible Opioid Prescribing, a Physician's Guide, by Dr. Scott M. Fishman (DEF-CA-101950)

Despite its date, the evidence shows, and the Court finds, that this document was used in California during the UCL limitations periods. The Court also finds that the Endo Defendants directly supported the preparation and publication of this document. Specifically, Ex. P-CA-000441 discusses "Endo's commitment on promoting education . . . " and that this commitment included "support[ing] the development of a handbook," specifically the document now in question.

This 74-page handbook is, as the title suggests, directed to healthcare practitioners. Reading all of the complained of statements in context, the Court finds none of them to be false or misleading.

In the Foreword Dr. James N. Thompson, President and CEO, Federation of State Medical Boards states: "Patients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication; to deprive them of optimal pain-relief certainly does them harm. Yet these same life-restoring medications carry the potential to do grave harm to patients who may be at risk for addiction and abuse." (.000005). There are numerous other citations in the handbook to the critical need to balance pain relief on the one hand with the attendant risks of the medication. The handbook notes that "Application of this information in any situation remains the professional responsibility of the practitioner." (.000003). Stated most simply, none of the complained of statements in this handbook, written by a doctor for use by doctors, are demonstrably factually inaccurate or can reasonably be characterized as false or misleading for purposes of FAL or UCL liability.

///

///

4. Teva USA

The Teva USA Appendix identifies 11 documents as containing false or misleading statements.

The Court addresses the documents in the sequence in which they are cited in the Teva USA Appendix.

Imagine the Possibilities, Fentora Fall Manager's Meeting presentation (P-CA-001758)

No evidence explains how any part of this document was used or published outside the company so as to constitute a false or misleading statement likely to deceive the recipient.

2014 Vantrela ER Launch Plan (CEX 003)

No evidence explains how any part of this document was used or published outside the company so as to constitute a false or misleading statement made or disseminated to the public and likely to deceive the recipient.

Fentora Sales Call Log (P-CA-001352)

Nothing in the document purports to contain or constitute a false or misleading statement.

Fentora Sales Call Log (P-CA-001396)

Nothing in the document purports to contain or constitute a false or misleading statement.

Fentora Targeting Report (P-CA-001511.002 - .024)

Nothing in the document purports to contain or constitute a false or misleading statement.

2006-2015 speaker program data (P-CA-001346)

Nothing in the document purports to contain or constitute a false or misleading statement made or disseminated to the public.

2019 Pain Matters Website (P-CA-00816)

At the risk of repetition, the Court notes that the statements in this document/website must be viewed in the context of all other statements/information contained therein. The Court finds nothing false or misleading in the statements cited from this document/website.

Discovery Channel Pain Matters Flyer (P-CA-001532)

The Court finds nothing false or misleading in the statement cited from this document.

2004-2018 Payments to Pain Organizations (P-CA-001459)

Nothing in the document purports to contain or constitute a false or misleading statement.

2012 to 2014 Grant requests (P-CA-001332)

Nothing in the document purports to contain or constitute a false or misleading statement made or disseminated to the public.

5. Cephalon Inc.

The Cephalon Appendix identifies 26 documents as containing false or misleading statements. Of those, only 2 are dated within the applicable limitations periods for the FAL (May 21, 2015) and UCL (May 21, 2014) claims. One (DEF-CA-101950) is dated earlier, but as noted earlier, there is evidence of its use during the limitations period. For the other documents, nothing in the documents, or in any testimony concerning them, establishes that they were used or referenced in any way during the limitations periods. To the extent that the Court could indulge the speculation that information from earlier documents may have found its way into later presentations, it would require still further speculation to determine precisely what may have been disseminated to the public.

The Court addresses the three documents in the sequence in which they are cited in the Cephalon Appendix.

Fentora Sales Call Log (P-CA-001352)

Nothing in the document purports to contain or constitute a false or misleading statement.

Fentora Sales Call Log (P-CA-001396)

Nothing in the document purports to contain or constitute a false or misleading statement.

Responsible Opioid Prescribing, a Physician's Guide, by Dr. Scott M. Fishman (DEF-CA-101950)

As already noted above, reading all of the complained of statements in context, the Court finds none of them to be false or misleading.

///

///

V. Conclusion

The Court finds that the People have failed to prove an actionable public nuisance for which Defendants, or any of them, are legally liable.

As the Court finds none of the identified statements, within the applicable limitations periods, to be false or misleading, the People's claims fail under both the FAL and UCL.

There will accordingly be judgment for Defendants on all claims.

Dated: 12/14/21

By: _____
Hon. Peter J. Wilson
Judge of the Superior Court